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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,223	07/11/2003	Eric K. Mangiardi	000100.0015	4411
37305	7590	06/12/2007		
ALSTON & BIRD LLP BANK OF AMERICA PLAZA 101 SOUTH TRYON STREET SUITE 4000 CHARLOTTE, NC 28280-4000			EXAMINER APANIUS, MICHAEL	
			ART UNIT 3736	PAPER NUMBER
			MAIL DATE 06/12/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/618,223

Applicant(s)

MANGIARDI ET AL.

Examiner

Michael Apanius

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-8,10-24,37 and 39-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-8,10-24,37 and 39-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 January 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                 | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. This Office Action is in response to the amendment and appeal brief filed on 3/26/2007. The amendment is entered. The cancellation of claim 43 is acknowledged.

2. In view of the Appeal Brief filed on 3/26/2007, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below. To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

3. A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below.

### ***Drawings***

4. The drawings are objected to because figure 11 is not numbered. The drawings are further objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "detents 170 or a lip 170" (page 10, line 9 and page 11, lines 10 and 13).

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5. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

6. The disclosure is objected to because of the following informalities: at page 6, line 22, it appears that --configuration-- should be added after inflated. Appropriate correction is required.

***Claim Objections***

7. Claims 1, 3-6, 15, 19, 20 and 37-42 are objected to because of the following informalities:

- a. At claim 1, line 3 and claim 37, line 3, it appears that "the same exploratory procedure" lacks proper antecedent basis in the claim.
- b. At claim 15, line 4, it appears that "length" should be --diameter--.
- c. At claim 19, line 2, it appears that "the first conduit" lacks proper antecedent basis in the claim.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 5, 12 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Independent claims 1, 7 and 37 recite that the inward facing surfaces of the legs are in flush contact with one another from the distal ends of the legs to the proximal ends of the legs when the measurement assembly is closed within the exterior conduit. Claims 5, 12 and 41 recite that the distal ends of the

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legs are coupled together as shown in the embodiment of figures 14-18. The original disclosure states, "when the legs are constrained by the exterior conduit 130 they lay substantially flush with respect to one another" (page 9, lines 16-17). However, this statement pertains to the embodiment of figures 1-13 when the distal ends of the legs are not coupled together. Regarding the embodiment of figures 14-18, the original disclosure states, "when the measurement assembly is retracted, the legs are relaxed and reside adjacent one another so that the legs may be retracted within the exterior conduit" (page 10, lines 23-26). However, the original disclosure does not appear to support inward facing surfaces of the legs in the embodiment of figures 14-18 being in flush contact with one another from the distal ends of the legs to the proximal ends of the legs when the measurement assembly is closed within the exterior conduit.

Therefore, the subject matter of claims 5, 12 and 41 does not appear to be properly supported by the original disclosure.

### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1, 3-8, 10-24, 37 and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain (5,919,147) in view of Colvin et al. (5,010,892) and Haddock et al. (US 6,712,771).

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12. Jain teaches a body lumen measuring device that is capable of allowing a user to calculate the length and diameter of a suitable interventional prosthesis as well as the height and length of stenosis during the same exploratory procedure. The device (10) includes an exterior conduit (22); an interior conduit (24) slidably disposed within the exterior conduit and having a depth marking mechanism (42); a measurement assembly (26 or 54) including a plurality of legs (44 or 56, 58) coupled with each other proximal the distal ends thereof and coupled about the distal end of the interior conduit; and a handle (24, 30) operatively connected with the measurement assembly. The handle includes means for opening and closing the measurement assembly by actuating the handle along a continuum between a first closed configuration and a second open configuration. The inward facing surfaces along a portion of the legs are in flush contact with one another along a portion distal of the proximal ends when the measurement assembly is closed within the exterior conduit (see figure 2). The legs form an acute angle with respect to one another as the measurement assembly is moved distally in relation to the first conduit (see figures 3 and 6). In an alternative embodiment, the distal ends of the legs are coupled together (see figures 5 and 6). The handle further includes the measurement indicator, wherein target lumen dimensions are calculated based on the relative distance the handle travels along the continuum between the first and second handle locations (column 1, lines 45-47). The device is used to measure a target segment of a lumen of a patient so as to select a suitable interventional prosthesis (column 1, lines 16-20). In operation, the device is introduced into an appropriate anatomical orifice of a patient; delivered adjacent a target segment of a

lumen within the patient; and the diameter of the target segment is measured within the patient (paragraph bridging columns 3 and 4). The device further comprises an optical scope to view placement of the measurement assembly (column 3, lines 57-58).

13. Jain teaches all of the limitations of the claims except that the exterior conduit has measurement markers formed on a portion thereof, that the depth markings on the interior conduit are visible through the exterior conduit, measuring length of a target segment, measuring dimensions of a stenotic segment, and that the inward facing surfaces of the legs are in flush contact with one another from the distal ends of the legs to the proximal ends of the legs when the measurement assembly is closed within the exterior conduit.

14. Colvin et al. teach a body lumen measuring device that is capable of allowing a user to calculate the length and diameter of a suitable interventional prosthesis as well as the height and length of stenosis during the same exploratory procedure. The device (10) includes an exterior conduit (12) having measurement markers (24) formed on a portion thereof; an interior conduit (16) slidably disposed within the exterior conduit and having a depth marking mechanism (22) which may be visible through a portion of the exterior conduit (20); a measurement assembly including a plurality of legs (54a-54c) coupled with each other proximal the distal ends thereof and coupled about the distal end of the interior conduit; and a handle (14) operatively connected with the measurement assembly. The handle includes means for opening and closing the measurement assembly (18) by actuating the handle along a continuum between a first closed configuration and a second open configuration. An optical endoscope may be



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operatively coupled therewith, so that the measuring step may be accomplished using the optical endoscope. The device may be used to measure the diameter and length of a target segment of the lumen within the patient, including the height and length of the stenosis (column 3, lines 65-66).

15. Applicant has not disclosed that using a measurement indicator arrangement having a plurality of measurement markers formed on a portion of the exterior conduit and a depth marking mechanism on the interior conduit that is visible through a portion of the exterior conduit solves any stated problem or is for any particular purpose. Moreover, it appears that the measurement indicator arrangement of Jain, or applicant's invention, would perform equally well with the plurality of measurement markers formed on a portion of the exterior conduit and a depth marking mechanism on the interior conduit that is visible through a portion of the exterior conduit, similar to the arrangement taught by Colvin et al. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified Jain to include a measurement indicator arrangement similar to that of Colvin et al, because such a modification would have been considered a mere design consideration which fails to patentably distinguish over Jain.

16. As noted above, Colvin et al. teach measuring height and length of body lumens including that of stenotic lumens to facilitate accurate sizing of a device to be placed in the lumen. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have measured the length of a target lumen and height and length of stenoses as taught by Colvin et al. in the method of Jain in order to obtain

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additional information about the proper size of a device to be inserted into a body lumen.

17. Haddock et al. disclose legs (302 in figures 3A-B or 310 in figure 3C) of a measurement assembly, wherein inward facing surfaces of the legs are in flush contact with one another from the distal ends of the legs to the proximal ends of the legs when the measurement assembly is closed within an exterior conduit (300). The flush legs of Haddock et al. would be advantageous since relative movement of the legs would be prevented when the legs are stored within the exterior conduit. Thus, potential damage to the legs would be avoided before the device is used. Furthermore, one of ordinary skill in the art would recognize that allowing the legs to be closed in flush contact along their entire lengths would allow the diameter of the conduit to be reduced allowing access to smaller lumens in the body. It would have been obvious to one having ordinary skill in the art at the time of invention to have modified the legs of Jain so that the legs are in flush contact along their entire lengths when the measurement assembly is closed within an exterior conduit as taught by Haddock et al. in order to prevent relative movement and damage to the legs before the legs are extended from the exterior conduit and to reduce the overall diameter of the conduit so that smaller body lumens can be accessed by the device.

### ***Response to Arguments***

18. Applicant's arguments, see the appeal brief, filed 3/26/2007, with respect to the prior art rejection set forth in the Office Action of 10/26/2006 have been fully considered

and are persuasive. Thus, the 35 U.S.C. §103 rejection of claims 1, 3-8, 10-24, 37 and 39-43 set forth in the previous Office Action has been withdrawn.

### ***Conclusion***

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Diamantopoulos et al. (US 2003/0120171) discloses a vascular temperature measuring device having sensors on resiliently biased projections (see figures 2 and 3).

20. Applicant's amendment filed 6/15/2006 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

21. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


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22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Apanius whose telephone number is (571) 272-5537. The examiner can normally be reached on Mon-Fri 8am-4:30pm.

23. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

24. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MA

  
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